

CLAIMS:

*Sub A1*  
1. A gas inflation/evacuation system removably connectable to a proximal portion of a guidewire assembly, comprising:

2. means for evacuating air from the guidewire assembly; and

3. means for introducing a biocompatible gas into the guidewire assembly to inflate an occlusive balloon proximate a distal end of the guidewire assembly a plurality of times; and

4. means for selectively sealing the proximal portion of the guidewire assembly at one of a plurality of separate locations to form one of a plurality of airtight seals of the guidewire assembly.

5. 2. The system of claim 1 wherein the gas inflation/evacuation system is a handheld apparatus.

6. 3. The system of claim 2 wherein the proximal portion of the guidewire assembly is selectively insertable into a first aperture of the handheld apparatus and the gas inflation/evacuation system is operably connected to a second aperture of the handheld apparatus, the handheld apparatus comprising an airtight passageway connecting the first aperture and the second aperture.

7. 4. The system of claim 1 wherein the means for sealing comprises a crimping mechanism.

8. 5. The system of claim 4 wherein the crimping mechanism comprises:

9. a first depressible roller and a second bias offset roller proximately spaced from the first roller for traversal of the guidewire, the first roller being connected to a depressible lever handle with a pivotable cam arrangement such that force on the handle causes the first roller to proportionately approach the offset second roller, a first threshold force on the handle sealing the

6 proximal portion of the guidewire and a second threshold force on the handle severing the  
7 proximal portion of the guidewire.

1 6. The system of claim 5 wherein the depressible lever handle is spring biased for an  
2 automatic return to an open starting position upon the cessation of a depressible force.

1 7. The system of claim 1 wherein the means for sealing comprises a plugging mechanism  
2 that selectively inserts a plug of material into the proximal portion of the guidewire assembly  
3 while maintaining an airtight seal between the guidewire assembly and the inflation/evacuation  
4 system.

1 8. The system of claim 1 wherein the inflation/evacuation system is contained in a sterile  
2 packaging.

1 9. The system of claim 8 wherein the sterile packaging is packaged in a vessel filled with a  
2 biocompatible gas and any gas within the sterile packaging when packaged is only the  
3 biocompatible gas.

1 10. A gas inflation/evacuation system removably connectable to a proximal portion of a  
2 guidewire assembly, comprising:

3 a first syringe system that selectively evacuates air from the guidewire assembly;  
4 and

5 a second syringe system that selectively introduces a biocompatible gas into the  
6 guidewire assembly to inflate an occlusive balloon proximate a distal end of the  
7 guidewire assembly a plurality of times; and

8 a sealing system removably connectable to the proximal portion of the guidewire  
9 assembly that selectively seals the proximate portion at one of a plurality of separate  
10 locations to form one of a plurality of airtight seals of the guidewire assembly.

1 11. The system of claim 10 wherein the gas inflation/evacuation system and the sealing  
2 system are arranged as parts of a handheld apparatus and the proximal portion of the guidewire  
3 assembly is selectively insertable into a first aperture of the handheld apparatus and the gas  
4 inflation system is operably connected to a second aperture of the handheld apparatus, the  
5 handheld apparatus comprising an airtight passageway connecting the first aperture and the  
6 second aperture.

1 12. The system of claim 10 wherein the sealing system comprises a crimping mechanism.

1 13. The system of claim 12 wherein the crimping mechanism comprises:  
2 a first depressible roller and a second bias offset roller proximately spaced from  
3 the first roller for traversal of the guidewire, the first roller being connected to a depressible lever  
4 handle with a pivotable cam arrangement such that force on the handle causes the first roller to  
5 proportionately approach the offset second roller, a first threshold force on the handle sealing the  
6 proximal portion of the guidewire and a second threshold force on the handle severing the  
7 proximal portion of the guidewire.

1 14. The system of claim 13 wherein the depressible lever handle is spring biased for an  
2 automatic return to an open starting position upon cessation of a depressible force.

1 15. The system of claim 10 wherein the sealing system comprises a plugging mechanism that  
2 selectively inserts a plug of material into the proximal portion while maintaining an airtight seal  
3 between the guidewire assembly and the inflation/evacuation system.

1 16. The system of claim 10 wherein the gas inflation/evacuation system is contained in a  
2 sterile packaging.

1 17. The system of claim 16 wherein the sterile packaging is packaged in a vessel filled with a  
2 biocompatible gas and any gas within the sterile packaging when packaged is only the  
3 biocompatible gas.

1 18. A gas inflation/deflation system selectively operably connectable to and removable from  
2 a proximal portion of a guidewire assembly, comprising:  
3           a hand-held structure having a first aperture and a second aperture with a lumen  
4           defined therebetween such that the proximal portion of the guidewire is insertable into  
5           the first aperture;  
6           a sealing mechanism housed within the handheld structure and positioned along at  
7           least a portion of the lumen to sealably engage the proximal portion of the guidewire;  
8           a crimping mechanism operably arranged to selectively crimp the guidewire at a  
9           point along the proximal portion of the guidewire;  
10          a first syringe system that selectively evacuates air from the guidewire assembly;  
11          a second syringe system containing a volume of a biocompatible gas sufficient to  
12          inflate an occlusive balloon proximate a distal end of the guidewire assembly a plurality  
13          of times; and  
14          conduits operably connecting the first syringe system and the second syringe  
15          system to the second aperture of the hand-held structure, the conduits including a valve  
16          arrangement that selectively connects only one of the first syringe system and the second  
17          syringe system to the second aperture at a time.

1 19. The system of claim 18 wherein the second syringe system includes a plurality of  
2 individual syringes, each individual syringe containing a sufficient volume of gas to inflate the  
3 occlusive balloon one time.

1 20. The system of claim 18 wherein the crimping mechanism comprises:  
2           a first depressible roller and a second bias offset roller proximately spaced from  
3           the first roller for traversal of the guidewire, the first roller being connected to a depressible lever

4 handle with a pivotable cam arrangement such that force on the handle causes the first roller to  
5 proportionately approach the offset second roller, a first threshold force on the handle sealing the  
6 proximal portion of the guidewire and a second threshold force on the handle severing the  
7 proximal portion of the guidewire.

1 21. The system of claim 20 wherein the depressible lever handle is spring biased for an  
2 automatic return to an open starting position upon cessation of a depressible force.

1 22. A gas inflation/evacuation system removably connectable to a proximal portion of a  
2 guidewire assembly, comprising:

3 a hand-held structure having a first aperture and a second aperture with a lumen  
4 defined therebetween such that the proximal portion of the guidewire is insertable into  
5 the first aperture;

6 a sealing mechanism housed within the handheld structure and positioned along at  
7 least a portion of the lumen to sealably engage the proximal portion of the guidewire;

8 a crimping mechanism operably arranged to selectively crimp the guidewire at a  
9 point along the proximal portion of the guidewire;

10 a first syringe system that selectively evacuates air from the guidewire assembly;  
11 and

12 a plurality of syringe systems, each syringe system containing a volume of a  
13 biocompatible gas sufficient to inflate an occlusive balloon proximate a distal end of the  
14 guidewire assembly a plurality of times.

1 23. The system of claim 22 further comprising:

2 conduits operably connecting the first syringe system and the plurality of syringe  
3 systems to the second aperture of the hand-held structure, the conduits including a valve  
4 arrangement that selectively connects only one of the first syringe system and the  
5 plurality of syringe systems to the second aperture at a time.

1 24. The system of claim 22 wherein the inflation/evacuation system is contained in a sterile  
2 packaging.

1 25. The system of claim 24 wherein the sterile packaging is packaged in a vessel filled with a  
2 biocompatible gas and any gas within the sterile packaging when packaged is only the  
3 biocompatible gas.

1 26. A method of using a gas inflation/evacuation system comprising the steps of:  
2 (a) attaching an inflation/evacuation system to a proximal portion of a guidewire  
assembly;  
3 (b) evacuating air from the guidewire with a first syringe system;  
4 (c) introducing a biocompatible gas under pressure into the guidewire with a second  
5 syringe system to inflate an occlusion balloon proximate a distal end of the guidewire;  
6 (d) inspecting a pressure gauge to monitor and control the introduction of the  
7 pressurized gas into the guidewire;  
8 (e) sealing a proximal portion of the guidewire;

1 27. The method of claim 26 wherein sealing the proximal portion of the guidewire is  
2 achieved by applying compressive force to a handle on a crimping mechanism thereby actuating a  
3 pivotable cam arrangement that crimps and then severs the proximal portion of the guidewire.

1 28. The method of claim 26 wherein sealing the proximal portion of the guidewire is  
2 achieved by inserting a sealant material into the proximal portion of the guidewire.

1 29. The method of claim 28 wherein the sealant material is selected from a group consisting  
2 of: wax, plastic, polymer or metal.

1 30. A method of packaging an inflation/evacuation system and a guidewire assembly  
2 comprising the steps of:

- 3           (a) placing components of the inflation/evacuation system and the guidewire into a  
4 sealed chamber with an atmosphere comprised of biocompatible gas;  
5           (b) assembling the inflation/evacuation system and the guidewire within the sealed  
6 chamber;  
7           (c) individually placing the inflation/evacuation system and the guidewire into  
8 biocompatible packaging as contents;  
9           (d) hermetically sealing each biocompatible packaging around its contents; and  
10          (e) removing the hermetically sealed packaging from the sealed chamber.

51       31. The method of claim 30 wherein the packaging is hermetically sealed so that the internal  
52 volume of both the packaging and the corresponding contents are comprised solely of  
53 biocompatible gas.

54       32. A gas inflation/evacuation system removably connectable to a proximal portion of a  
55 guidewire assembly, comprising:

56           a first syringe system that selectively evacuates air from the guidewire assembly;  
57 and

58           a second syringe system that selectively introduces a biocompatible gas into the  
59 guidewire assembly to inflate an occlusive balloon proximate a distal end of the  
60 guidewire assembly a plurality of times; and

61           a sealing system removably connectable to a the proximal portion of the  
62 guidewire assembly that selectively seals the proximal portion of the guidewire assembly  
63 at one of a plurality of separate locations to form one of a plurality of airtight seals of the  
64 guidewire assembly, including:

65           a first aperture and a second aperture in fluid communication, the first  
66 aperture capable of receiving the proximal portion of the guidewire, the second aperture  
67 removably attachable to a conduit;

15                   an operational o-ring in coaxial alignment and contained within the first  
16                   aperture for operational engagement of the guidewire some insertion distance through the  
17                   first aperture;

18                   a sealant o-ring in coaxial alignment and contained within the first  
19                   aperture whereby it is distally spaced from the operational o-ring such that further  
20                   insertion of the guidewire into the body, through the first aperture, and past the  
21                   operational o-ring will bring the guidewire into engagement with the sealant o-ring; and

22                   a sealant containment layer for receiving the guidewire some distance past  
23                   the insertion of the guidewire through the sealant o-ring whereby the sealant containment  
24                   layer includes sealant material such that insertion of the guidewire into the sealant  
25                   containment layer and into the sealant material forces the sealant material into the  
26                   proximal portion of the guidewire.

33. The system of claim 32 wherein the sealant material is selected from the group consisting  
of: wax, plastic, polymer, and metal.